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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/900,627	07/06/2001	Charles David Weaver	3035-4086US1	7563

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EXAMINER	
CHEU, CHANGHWA J	

ART UNIT	PAPER NUMBER
1641	

DATE MAILED: 08/26/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/900,627	WEAVER ET AL.	
	Examiner	Art Unit	
	Jacob Cheu	1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *21 June 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-31* is/are pending in the application.

4a) Of the above claim(s) *32-120* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-31* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Applicant's amendment filed on 6/21/2004 has been received and entered into record and considered.

The following information provided in the amendment affects the instant application:

Claims 1, 11 and 27 are amended.

Currently, claims 1-31 are under examination. Claims 32-120 are withdrawn from further consideration.

Claim Rejections - 35 USC § 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 1-29 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1-29 are vague and confusing. These claims recite an apparatus for measuring cellular electrical conditions in their preamble but fail to recite any means, such as electrodes, to carry out the purported measurements of any electrical signals.

With respect to claim 1 ~~all the claims~~, "Cell Support Membrane component *adapted to*" is vague and indefinite. It is not clear as to how the Cell Support Membrane is modified to perform the recited functions.

With respect to all of the claims ~~claim 1~~, the phrase "Cell Support Membrane' is vague and indefinite. Is it a trademark type of membrane? If not, applicant is advised to replace the capitalized form of description.

With respect to claim 1, the actual spatial relationship of the "second layer" is not clear relative to the "first layer". In step (ii) applicant merely stipulates that the second layer "contacts" the first layer and spans across at least one pore. Is this "second layer" positioned on the same side of the "first layer" that is for attachment of cells or on the opposite side of the "first layer"?

Claims 6 and 7 are vague and indefinite since it is not clear as to how a dye can be a non-conductive" material. Dyes contain materials that are conductive in nature, such as water. Moreover, it is not clear what is the purpose of the recited dye in the claim. It is not clear the relationship between the recited dye and the cellular electrical measurement apparatus. Claim 7 is further vague and indefinite because it recites a trademark compound Solvent Blue 14 without the generic terminology to define its composition.

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical

Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

2. Claims 1, 12-14 are rejected under 35 U.S.C. 102(b) as being anticipated by Carnow et al. (J Neuroscience 1985 5: 1965).

Carnow et al. teach placing a nitrocellulose paper (with 0.45 μm pore size) in a plastic tubing for analysis of ciliary neuronotrophic factor protein (See Abstract, Materials and Methods, page 1965, right column, last paragraph). The structure arrangement has two layers. First layer is the nitrocellulose paper with pores of 0.45 μm capable of electrically tight seals with contact cells. The second layer is a non-conductive plastic tubing underneath the nitrocellulose paper and spans across at least one hole. Applicant is reminded that a recitation of the intended use of the claimed invention, i.e. measuring cellular electrical conditions, must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. In a claim drawn to a process of making, the intended use must result in a manipulative difference as compared to the prior art. See In re Casey, 152 USPQ 235 (CCPA 1967) and In re Otto, 136 USPQ 458, 459 (CCPA 1963). The teachings of Carnow et al. would inherently capable of performing the purported purpose as recited in the instant claim since all the features are encompassed in the art.

3. Claims 1-4, 8-9, 12-13, 28-31 are rejected under 35 U.S.C. 102(e) as being anticipated by Baumann et al (US 6475760).

Baumann et al. teach using an apparatus for measuring intracellular manipulations of a biological cell, e.g. electrophoration of cells to determine membrane potential (See Figure 1). The apparatus comprising two layers wherein the first layer having non-conductive materials with plurality of pores (concave between component 5 in Figure 8) for cell attachment, and a second sealant layer (component 9 in Figure 8) comprises a non-porous layer in contact the cell support membrane. The arrangement of the two layers can seal the cell membrane against the pore areas (Col. 11, line 1-10). The second layer contacts the first layer and spaning across at least one pores (See Figure 8). The device can be coated with glass, plastic or silicon (Col. 9, line 38-45). Additionally, Baumann et al. also teach permealizing cell membrane with Triton® and coating the device with fibronectin, Poly-L-lysine for facilitation of cell attachment (Col. 3, line 30-32; Col. 6, line 27-37).

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

5. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

6. Claims 15-18 and 19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Baumann et al. in view of Owen et al. (WO 99/66329).

Baumann et al. reference has been discussed but is silent in specifying particular cell type applicable for electrical condition measurement. Additionally, Baumann et al. also do not explicitly reveal the diameter of the pores for cell attachment. Owen et al. teach a high throughput screening method by using an apparatus comprising a biological membrane onto a plurality of pores (See Figure 1A and 1B). The reference of Owen et al. is an analogous art to that of Baumann et al. because the purported technology directs to the measurement of cellular electrical conditions, e.g. K+ channel polralization or depolarization of cellular ion channel proteins across biological membranes (See page 5, line 12-19; page 10, line 10-25). Cells involving electriophysiology are applicable for this measurements include primary neuronal tissue, such as hippocampus, dorsal root, or skeletal muscle, smooth muscle; cardiac muscle or endothelial cells (See page 8, line 10-17). Therefore, it would have been obvious to have motivated one skilled in the art at the time when invention was made to apply the measurements of cellular electrical conditions in different types of cells as taught by Owen et al. with reasonable expectation of success because the art is in the same field and applying to different samples merely involves routine skilled in the art.

7. Claims 10-11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Baumann et al in view of Bossuyt et al. (US 6585969).

Baumann et al. reference discloses using fibronectin or Poly-L-lysine to facilitate cell attachment around the adjacent of the poration tool of the apparatus (Figure 1; Col. 6, line 25-35). Nonetheless, Baumann et al. do not explicitly teach using materials, such as silicone or Teflon, to inhibit cell attachment. Bossuyt et al. teach treating the cell culture vessel with silicone will make the walls sufficiently hydrophobic to prevent cell adhesion for cell culturing (Col. 14, last paragraph to

Col. 15, line 1-2). Therefore, it would have been obvious to have motivated one skilled in the art at the time when invention was made to apply the treatment of silicone to the outside of the cell attachment site as taught by Bossuyt et al. to further increase cell attachment to the target area because silicone treatment to the outside of the cell attachment site can prevent cell from adhesion outside of the electrical measurement area and cause more specific and efficient cell attachment to the electrical measurement area.

Response to Applicant's Arguments

8. The rejections of claims 1-4, 6-9, 12-13, 20, 28-31 under 35 USC 102 (b) as anticipated by Baumann et al. are maintained.

Applicant amended claim 1 with the feature of the second layer "spans across at least one pore" to overcome the 102 (b) rejection. Applicant's arguments have been considered but are not persuasive. It has been shown in this Office Action that Baumann et al. reference also containing this feature. Examiner interprets Baumann et al reference broadly since component 5 is the first layer with pores and component 9 is the second sealant layer is in contact with the first layer (See Figure 8).

9. The rejections of claims 14-18 and 19 under 35 USC 103 (a) as unpatentable over Baumann et al in view of Owen et al. are maintained.

Applicant argues that Owen et al. reference does not teach using a non-conductive layer to span across at least one pore of its structure. Again, this Office Action already established that the second layer of Baumann et al., i.e. non-conductive layer, spans across at least one pore from the structure.

10. Applicant's arguments with respect to claims 10-11 have been considered but are moot in view of the new ground(s) of rejection.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jacob Cheu whose telephone number is 571-282-0814. The examiner can normally be reached on 9:00-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on 571-272-0823. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Jacob Cheu
Examiner
Art Unit 1641

August 24, 2004

CHRISTOPHER L. CHIN
PRIMARY EXAMINER
GROUP ~~1800~~ 1641
8/24/04